



## Medical Pharmacy Drug Prior Authorization Criteria

<b>Drug Trade Name:</b>	Cosentyx® IV	<b>Drug Generic Name:</b>	Secukinumab
<b>J Code:</b>	J3247	<b>1 billable unit =</b>	1 mg
<b>Original Date of Review:</b>	9/10/2025	<b>Last Reviewed:</b>	9/10/2025
<b>Revision Date History</b>	9/10/2025		

Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory immune responses. Secukinumab inhibits the release of proinflammatory cytokines.

**Criteria:**

- **Length of authorization:**
  - Initial: 6 months
  - Renewal: Up to 12 months
- **Age:** 18 years and older
- **Diagnoses [including ICD-10 codes]:** see below
- **Quantity Limit:**
  - Loading Dose:
    - Cosentyx® 6 mg/kg IV at weeks 0
  - Maintenance Dose:
    - Cosentyx® 1.75 mg/kg IV every 4 weeks (28 days)
- **Maximum Units:**

Indication	Billable Units	Per Number of Days
All Loading Dose	750	28
All Maintenance	300	28

- **Initial Approval Criteria**
  - **Universal Criteria [if applicable]**
    - Coverage is provided in the following conditions:
    - Patient is at least 18 years of age; **AND**
    - Provider attests that patient is up to date with all vaccinations, in accordance with current immunization guidelines, prior to initiating therapy; **AND**
    - Clinical documentation physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
    - Provider attests that the patient will be screened for active infection, including clinically important localized infections, prior to each administration of this medication; **AND**

- Clinical documentation patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
    - Provider attests patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); **AND**
  - **Indication Specific Criteria [if applicable]**
    - **Ankylosing Spondylitis**
      - Documented active disease; **AND**
      - Clinical documentation patient had an adequate trial and failure of at least TWO non-steroidal anti-inflammatory agent (NSAIDs) over 4 weeks in total, unless contraindicated
    - **Adult Psoriatic Arthritis**
      - Documented moderate to severe active disease; **AND**
      - For patients with predominantly axial disease, clinical documentation patient had a 4 week trial and failure of ONE non-steroidal anti-inflammatory agent (NSAID), unless use is contraindicated; **OR**
      - For patients with peripheral arthritis, dactylitis OR active enthesitis, clinical documentation patient had a 3-month trial of ONE oral disease modifying anti-rheumatic agent (DMARD) (e.g. methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine etc.
    - **Non-Radiographic Axial Spondyloarthritis**
      - Clinical documentation patient has objective signs of inflammation noted by an elevation of C-reactive protein (CRP) above the upper limit of normal and sacroiliitis on MRI **AND**
      - Clinical documentation patient is without definitive radiographic evidence of structural damage on sacroiliac joints; **AND**
      - Documented active disease; **AND**
      - Clinical documentation patient had an adequate trial and failure of at least TWO non-steroidal anti-inflammatory agent (NSAIDs) over 4 weeks in total, unless contraindicated
- **Renewal Criteria**
  - Coverage may be renewed based upon the following criteria:
    - Patient continues to meet universal and indication-specific criteria as identified in Initial Approval Criteria; **AND**
    - Provider attests patient has not experienced any unacceptable toxicities from the drug.
      - Examples of unacceptable toxicities include: anaphylaxis or other serious allergic, severe infusion-related or hypersensitivity reactions, severe infections, progressive multifocal leukoencephalopathy (PML), jaundice or other evidence of significant liver injury, etc.; **AND**
  - **Ankylosing Spondylitis**
    - Documentation of positive clinical response
  - **Adult Psoriatic Arthritis**
    - Documentation of positive clinical response
  - **Non-Radiographic Axial Spondyloarthritis**
    - Documentation of positive clinical response

- **Dosage/Administration**

<b>Cosentyx® (Intravenous)</b>	
<b>Indication</b>	<b>Dose</b>
Ankylosing Spondylitis	<p><u>With a Loading dose:</u> Administer 6 mg/kg given at week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter (max maintenance dose 300 mg per infusion)</p> <p><u>Without a Loading dose:</u> Administer 1.75 mg/kg every 4 weeks (max maintenance dose 300 mg per infusion)</p>
Psoriatic Arthritis (Adult)	<p><u>With a Loading dose:</u> Administer 6 mg/kg given at week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter (max maintenance dose 300 mg per infusion)</p> <p><u>Without a Loading dose:</u> Administer 1.75 mg/kg every 4 weeks (max maintenance dose 300 mg per infusion)</p>
Non-Radiographic Axial Spondyloarthritis	<p><u>With a Loading dose:</u> Administer 6 mg/kg given at week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter (max maintenance dose 300 mg per infusion)</p> <p><u>Without a Loading dose:</u> Administer 1.75 mg/kg every 4 weeks (max maintenance dose 300 mg per infusion)</p>

**NDC:**

- Cosentyx® 125 mg/5 ml single use vial: 0078-1168-61

**References:**

1. Cosentyx [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corp.; October 2023.
2. Ward MM, Deodhar, A, Gensler, LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis & Rheumatology*. 2019; 71(10): 1599-1613.
3. Yu, DT, van Tubergen A. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. Sieper, J (Ed). UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com>. Accessed on February 21, 2024.
4. Singh, JA, Guyatt, G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis & Rheumatology*. 2019; 71(1): 5-32.

## Covered Diagnosis Codes – Intravenous (J3247)

ICD-10	ICD-10 Description	FDA vs Off-Label
L40.50	Arthropathic psoriasis, unspecified	FDA
L40.51	Distal interphalangeal psoriatic arthropathy	FDA
L40.52	Psoriatic arthritis mutilans	FDA
L40.53	Psoriatic spondylitis	FDA
L40.59	Other psoriatic arthropathy	FDA
M45.0	Ankylosing spondylitis of multiple sites in spine	FDA
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region	FDA
M45.2	Ankylosing spondylitis of cervical region	FDA
M45.3	Ankylosing spondylitis of cervicothoracic region	FDA
M45.4	Ankylosing spondylitis of thoracic region	FDA
M45.5	Ankylosing spondylitis of thoracolumbar region	FDA
M45.6	Ankylosing spondylitis lumbar region	FDA
M45.7	Ankylosing spondylitis of lumbosacral region	FDA
M45.8	Ankylosing spondylitis sacral and sacrococcygeal region	FDA
M45.9	Ankylosing spondylitis of unspecified sites in spine	FDA
M45.A0	Non-radiographic axial spondyloarthritis of unspecified sites in spine	FDA
M45.A1	Non-radiographic axial spondyloarthritis of occipito-atlanto-axial region	FDA
M45.A2	Non-radiographic axial spondyloarthritis of cervical region	FDA
M45.A3	Non-radiographic axial spondyloarthritis of cervicothoracic region	FDA
M45.A4	Non-radiographic axial spondyloarthritis of thoracic region	FDA
M45.A5	Non-radiographic axial spondyloarthritis of thoracolumbar region	FDA
M45.A6	Non-radiographic axial spondyloarthritis of lumbar region	FDA
M45.A7	Non-radiographic axial spondyloarthritis of lumbosacral region	FDA
M45.A8	Non-radiographic axial spondyloarthritis of sacral and sacrococcygeal region	FDA
M45.AB	Non-radiographic axial spondyloarthritis of multiple sites in spine	FDA